

9/463586

Docket No.: 515-4183

420 Rec'd PCT/PTO 25 JAN 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Maurizio Valeri et al) Group Art Unit:
Serial No.: not known) Examiner:
Filed: not known)

For: PHARMACEUTICAL COMPOSITIONS CONTAINING VITAMIN D AND
CALCIUM, THEIR PREPARATION AND THERAPEUTIC USE

New York, NY 10036
January 25, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

This Amendment is being filed to reduce the filing
fee of the above identified application. Kindly amend the
subject application as follows:

IN THE CLAIMS

Kindly amend claims 3, 13 and 14 under the provisions of 37
CFR§1.121(a) by deleting the bracketed subject matter and
inserting the underlined material;

3. (amended) Pharmaceutical composition according to Claim[s]
1 [and 2], in which the calcium salt is calcium phosphate.

13. (amended) Process for the preparation of a pharmaceutical
composition according to Claim[s] 1 [and 7], characterized by
the following steps:

- a) In a granulator turning at high speed, distribut[el]ing the
binding agent, consisting of propylene glycol or low
molecular-weight polyethylene glycols over the calcium
salt[.];
b) Adding the colloidal silica, approximately 25% of the
mannite, the citric acid, and the sodium saccharin, and mixing

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for the time required and at the appropriate speed[.];
c) Adding the mixture, prepared separately, consisting of
sucrose palmitate, a suspending agent, flavoring, colouring
agent, the remaining part of the mannite and the Vitamin D₃,
and mixing together with the rest of the preparation[.]; and
d) Distributeing the granulate thus obtained into bags.

14. (amended) Process for the preparation of a pharmaceutical
composition according to Claim[s] 1 [and 8], characterized by
the following steps:

- a) In a granulator turning at high speed, [distribute] placing
the binding agent, consisting of liquid parafin or silicon
oil, over the calcium salt[.];
b) Adding in order, to a mixture of colloidal silica,
carboxymethyl cellulose and sodium saccharin previously
sifted, the Vitamin D₃ and the sorbitol, mixing thoroughly
every time before a new ingredient is added [.], and
[P]pouring the mixture into the rotating granulator and mixing
for the required time and at the appropriate speed[.]; and
c) Compressing the granulate to the required weight to obtain
the desired tablets.

REMARKS

This Amendment is being filed to delete the multiple
dependent claims and reduce the filing fee. It is requested
that this Amendment be entered prior to calculating the filing
fee.

Respectfully submitted,



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